

**REMARKS**

Claims 1 to 39 are pending. Claims 40 to 50 are currently canceled. No amendments have been made, and no new claims have been added. Reconsideration of the application is requested.

**§ 103 Rejections**

A. Claims 1-5 and 7-39 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,780,047 (“Kamiya”) in view of U.S. Patent No. 4,855,142 (“Fankhauser”). Applicants respectfully disagree for at least the reason that the Examiner has failed to establish a *prima facie* case of obviousness.

1. Independent Claim 1 and Dependent Claims 2-5 and 7-14

Claim 1 recites “[a] device for delivering at least one active agent to a localized body surface comprising: a cold water-soluble carrier comprising at least one polymer and at least one plasticizer and having a first surface and a second surface, wherein the cold water-soluble carrier comprises film, fabric, tape or combinations thereof; a cold water-soluble adhesive disposed on at least a portion of the first surface of the carrier, and having a carrier surface in contact with first surface of the carrier and an application surface opposed to the carrier surface; and a support layer releasably adhered to the second surface of the carrier.”

The Examiner contends it would have been obvious to combine the plasticizer of Fankhauser with the device of Kamiya to arrive at the device recited in claim 1 (see Office Action, page 5, paragraphs 3-4). However, this thinking is flawed for at least two reasons.

First, the Examiner argues that “Fankhauser teaches a pharmaceutical plaster consisting of two discrete layers comprising (a) a cover film and (b) an adhesive layer (see col. 2, lines 5-8). *The cover film (reading on the carrier of instant claims 1 and 15) consists of a polyvinyl alcohol (reading on the polymer of instant claims 1 and 15) and a plasticizer* (see col. 2, lines 9-12).” Office Action, page 5, paragraph 4, emphases added. However, the cover film of Fankhauser does not read on the carrier of the instant claim 1.

Claim 1 recites “a cold water-soluble carrier comprising at least one polymer and at least one plasticizer.” Examples of suitable polymers include polymers of polyvinyl alcohols (see Present Application, page 7, lines 17-18). However, whether a polymer of polyvinyl alcohol results in a cold-water soluble carrier depends, in part, on the hydrolysis level of the polymer. As noted in the Present Application, polymers of polyvinyl alcohols can be commercially obtained in a variety of molecular weights and hydrolysis levels (see Present Application, page 7, lines 21-22). “The hydrolysis level determines, in part, whether the polymer is cold water-soluble or warm water-soluble, with hydrolysis greater than about 87% resulting in more crystalline polymers, thereby requiring higher temperatures to dissolve the polymer,” (see Present Application, page 7, lines 22-25). Therefore, not all polymers of polyvinyl alcohols lead to cold water-soluble carriers.

In contrast, Fankhauser discloses a pharmaceutical plaster consisting of two discrete layers, one of which is a cover film containing a *polyvinyl alcohol that is insoluble in cold water* (see, e.g., Fankhauser, col. 2, lines 5-27, emphasis added). In one embodiment, the polyvinyl alcohol has a maximum of 10% of the hydroxyl groups in the form of acetate groups which corresponds to a polyvinyl alcohol having a degree of hydrolysis of at least 90% (see Fankhauser, col. 2, lines 10-12 and 33-36). Fankhauser further recites that “[i]n the polyvinyl alcohol used preferably a maximum of 8% (degree of hydrolysis at least 92%), especially a maximum of 5% (degree of hydrolysis at least 95%) and more especially a maximum of 2% (degree of hydrolysis at least 98%) of the hydroxyl groups are in the form of acetate groups,” (Fankhauser, col. 2, lines 42-47).

The plaster according to Fankhauser “is distinguished by the fact that *both layers[including the cover film] are insoluble at body temperature*. This means that this plaster adheres to the mucosa, especially to the mucosa of the mouth, more reliably and for a longer period than does any other known preparation.” Fankhauser, col. 4, lines 62-68. In practice, “[i]f the patient does not remove the plaster at all it will eventually fall off and the patient will then be able to remove it from the mouth or to swallow it,” (see Fankhauser, col. 5, lines 19-22).

As evidenced above, the cover film of Fankhauser is not cold water-soluble. Therefore, the cover film of Fankhauser cannot read on the cold water-soluble carrier of instant claim 1 as argued by the Examiner.

Second, neither Kamiya nor Fankhauser, alone or in combination, teach or disclose a device in which a support layer is attached to a cold water-soluble carrier on the surface opposite a cold water-soluble adhesive layer, i.e. a construction of 1) support layer, 2) cold water-soluble carrier, and 3) cold water-soluble adhesive, as recited in amended claim 1.

The Examiner argues in his Response to Arguments that “Fankhauser teaches a carrier film and an adhesive. Fankhauser does not teach a releasable support layer, however, use of a releasable support layer with two water-soluble layers is taught by Kamiya (see col. 6, lines 35-44).” See Office Action, page 7, paragraph 4.

As already noted above, Fankhauser does not teach a cold water-soluble carrier as recited in claim 1. Additionally, Fankhauser does not teach a cold water-soluble adhesive. Therefore, even if one could find a basis for combining the peelable sheet of Kamiya with the cover film and adhesive of Fankhauser, the resultant device would not read on claim 1.

Additionally, Kamiya does not teach a device having the construction of 1) support layer, 2) cold water-soluble carrier, and 3) cold water-soluble adhesive. The Examiner specifically referenced Kamiya, col. 6, lines 35-44, as evidence of a releasable support layer with two water-soluble layers. This citation describes two methods:

a method that when the peelable sheet(s) (c) are provided on the adhesive sheet (a), one peelable sheet (c) of one side is peeled off to apply to human body and then the peelable sheet (c) of another side is peeled off upon taking a bath to obtain the bathing effect; [and]

a method that when the sheet (b) is provided on one side surface of the adhesive sheet (a) and the peelable sheet (c) is provided on another side surface, the peelable sheet (c) of one side is peeled off to apply to human body and then to the maintained, as it is, upon taking a bath.

The first recited method describes a device having the construction of 1) peelable sheet, 2) adhesive, and 3) peelable sheet. The second recited method describes 1) water-soluble protective material, 2) adhesive, and 3) peelable sheet.

Neither of the above devices read on a construction of 1) support layer, 2) cold water-soluble carrier, and 3) cold water-soluble adhesive, as recited in claim 1.

Since the Examiner's basis for rejecting claim 1 lies on the mistaken notions that the cover film of Fankhauser reads on the cold water-soluble carrier film of the instant claim 1 and that the combination of Kamiya and Fankhauser disclose a construction of 1) support layer, 2) cold water-soluble carrier, and 3) cold water-soluble adhesive, the requirement for a *prima facie* case of obviousness has not been met

Therefore, for at least the reasons provided above, independent claim 1 is patentable over Kamiya in view of Fankhauser. Claims 2-5 and 7-14 each add additional features to claim 1. Therefore, claims 2-5 and 7-14 are also patentable over Kamiya in view of Fankhauser.

2. Independent Claim 15 and Dependent claims 16-39

Claim 15 recites "[a] system for delivering at least one active agent to a localized body surface comprising: a cold water-soluble carrier comprising at least one polymer and at least one plasticizer, and having a first surface and a second surface, wherein the cold water-soluble carrier comprises film, fabric, tape or combinations thereof; a cold water-soluble adhesive disposed on at least a portion of the first surface of the carrier, and having a carrier surface in contact with first surface of the carrier, and an application surface opposed to the carrier surface; at least one active agent in association with the carrier, the adhesive, or both; and a support layer releasably adhered to the second surface of the carrier."

The Examiner's basis for rejecting claim 15 lies on the mistaken notions that the cover film of Fankhauser reads on the cold water-soluble carrier film of the instant claim 15 and that the combination of Kamiya and Fankhauser disclose a construction of 1) support layer, 2) cold water-soluble carrier, and 3) cold water-soluble adhesive. Therefore, for the same and similar reasons discussed above with respect to claim 1, the requirement for a *prima facie* case of obviousness has not been met with respect to claim 15.

For at least the reasons provided above, independent claim 15 is patentable over Kamiya in view of Fankhauser. Claims 16-39 each add additional features to claim 15. Therefore, claims 16-39 are also patentable over Kamiya in view of Fankhauser.

B. Claims 1 and 6 are rejected under 35 USC § 103(a) as being unpatentable over Kamiya in view of Fankhauser and in further view of U.S. Patent No. 5,028,435 ("Katz").

As discussed above with respect to claim 1, neither Kamiya nor Fankhauser, alone or in combination teach or disclose the device of claim 1. Katz fails to remedy the defects cited above with respect to Kamiya and Fankhauser. Therefore, for at least the reasons cited above, independent claim 1 is patentable over Kamiya in view of Fankhauser and in further view of Katz. Claim 6 adds additional features to claim 1. Therefore, claim 6 is also patentable over Kamiya in view of Fankhauser and in further view of Katz.

In view of the above, it is submitted that the application is in condition for allowance. Examination and reconsideration of the application is requested.

Applicants would welcome a telephonic interview with the Examiner prior to issuance of the next communication in order to efficiently advance the prosecution of this case.

Respectfully submitted,

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Date

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